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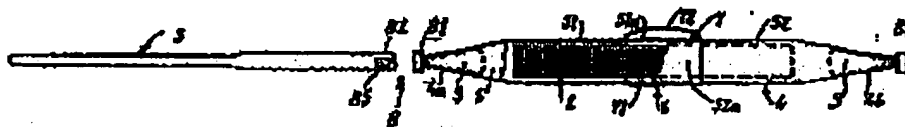
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(54) Title: SUB-URETHRAL SUPPORTING ASSEMBLY FOR TREATING FEMALE STRESS URINARY INCONTINENCE



(57) Abstract: The invention concerns a surgical assembly for supporting the urethra (1) in a woman, comprising a sub-urethral supporting tape (2) and a skin penetrating needle (3). The invention is characterized in that when combined: a) a composite strip (4) comprises at least both the sub-urethral supporting tape (2) and a flattened protective sheath (5) wherein said tape is arranged; b) the flattened sheath (5) comprises, lengthwise, two parts (31, 32) arranged on either side of a separation zone (6) wherein is provided elastic locking means (7) between the two parts; c) the composite strip (4) comprises at each of its two ends (4a, 4b) a connection part (81), for example a female part, of connecting means (8) capable of being locked and unlocked, while the proximal tip (31) of the skin penetrating needle (3) comprises another part (82), for example a male part, of said connection means (8).

SUB-URETHRAL SUPPORTING ASSEMBLY FOR TREATING FEMALE STRESS URINARY INCONTINENCE

The present invention concerns the surgical treatment of female stress urinary incontinence.

More particularly, the invention concerns a surgical assembly enabling, at the end of the intervention or operation, the supporting of the urethra by means of a sub-urethral tape, whose two ends are each attached to a suitable portion of the patient's body, for example, to her abdominal wall.

For this, in a general manner, the surgical assembly contemplated by the present invention comprises a sub-urethral support tape and a skin penetrating needle, this needle allowing the grasping and the pulling of the sub-urethral support tape.

The purpose of the present invention is a surgical assembly as defined above, of universal nature, in that it can be used regardless of the manner of approach, or the operating technique used by the practitioner.

For this, a surgical assembly according to the invention presents, in combination, the following characteristics:

- a) it has a composite strip which assembles at least the sub-urethral support tape and a flattened protection sheath, said strip being arranged, for example, freely inside this sheath;

- b) the flattened sheath comprises, along its length, two parts arranged on either side of a zone of separation, in which is arranged a cleavable linking means between said two parts;
- c) the composite strip comprises the same part at each of its two ends, for example, the same female part, of a means of connection that can be locked and unlocked, while the proximal tip of the skin penetrating needle contains another part, for example, a male part, of said means of connection.

For one of the routes selected by the surgeon, for example, the upper route, the assembly comprises, possibly in addition, a flexible, flat, atraumatic junction part for two pieces of the support tape, obtained by transverse cutting of the latter. And this junction part contains two opposing means of grasping the two adjacent ends of the two pieces, respectively, of the support tape.

The present invention is now described with reference to the enclosed drawing, in which:

- Figure 1 shows, in front view, a surgical assembly according to the invention,
- Figure 2 shows, in side view, the surgical assembly shown in Fig. 1,
- Figure 3 shows, in sectional view, a means of connection with the skin penetrating needle, belonging to the surgical assembly represented per Fig. 1 and 2,
- Figure 4 shows, in top view, a junction part for two pieces of the support tape, which can be part of the surgical assembly according to the invention,

- Figure 5 shows, in side view, the junction part represented in Fig. 7, with its two opposing means of grasping in the open position,
- Figures 6 through 9 show the different phases of implementing a surgical assembly according to the invention, by the lower route,
- Figures 10 through 13 show the different phases of implementing a surgical assembly according to the invention, by a so-called combined route,
- Figures 14 through 21 show the different phases of implementing a surgical assembly according to the invention, by the upper route.

According to figures 1 to 3, a surgical assembly according to the invention comprises at least:

- a composite strip 4 containing two tapered ends 4a, 4b, triangular in shape, flat,
- and a skin penetrating needle 3, having a distal penetrating end 32 and a flattened proximal tip 31.

The composite strip 4 assembles at least a sub-urethral support tape 2, two joining pieces 9, and a flattened protection sheath 5, inside which the tape 2 is freely arranged, that is, without being attached to the sheath 5.

The support tape 2 comprises a fillet stitch fabric, preferably run-proof, obtained with monofilaments or multifilaments of biocompatible synthetic material, for example, polypropylene or polyester.

The tape 2 is preferably formed from a macroporous knitted material.

This latter is, for example, a fillet stitch fabric of polypropylene monothread, having a thickness between 0.12 and 0.16 millimeters and composed of two layers formed by two guide bars, each one threaded with one full heddle and one empty heddle, these two bars being displaced symmetrically in open meshes according to the following pattern:

- bar I: 01-12-32
- bar II: 32-21-01

The tape 2 is cut lengthwise in the direction of the knitting warp. In the case of a length of 12 mm, it presents the following characteristics:

- a breaking strength in the direction of the warp of 105 N +/- 20%,
- an elongation at rupture in the direction of the warp of 92% +/- 20%,
- an elongation under 20 N of 36%,
- an onset of curling with a force of 6 N and an elongation of 15%.

By "curling" is meant the spontaneous roll-up of the tape 2 on itself, about its lengthwise axis, under constraint in longitudinal tension.

The tape 2 has interesting advantages and in particular a low emission of particles during elastic expansion, as well as a curling which only appears under a significant force (6 N). Neither of these mentioned characteristics in any way changes the porosity of the tape 2.

The latter can also be made in whole or in part from biological material or tissue, for example, collagen.

The flattened protection sheath 5 is obtained from a synthetic material with low coefficient of friction, for example, PTFE. This sheath 5 has two parts 51 and 52, along its length, arranged at either side of a separation zone 6, in which is arranged a cleavable linking means 7 between said two parts.

The composite strip 4 has at each of its two ends 4a and 4b an identical part, namely, an identical female part 81, of a means of connection 8, which can be locked and unlocked at will, while the proximal tip 31 of the skin penetrating needle 3 has another part, for example, a male part 82, of the same means of connection 8.

For this purpose, the flattened sheath 5 contains or incorporates, at its two respective ends, two joining pieces 9, each one containing or incorporating outside the sheath 5 the identical female part 81 of the means of connection 8.

This means of connection 8 thus comprises two elements, a male element 82 situated at either end 4a or 4b of the composite strip 4, and a female element 81 situated at the proximal tip 31 of the needle 3, these two elements, male and female, being able to snap together.

More precisely, as shown in particular by figure 3, the proximal tip 31 of the skin penetrating needle 3 is spatulate, and each joining piece 9 of the composite strip 4 contains,

outside the flattened sheath 5, a slit 83 adapted to the penetration of the proximal spatulate tip 31 of the needle 3, with a means 84 of retention of the tip 31, which can be manually locked or unlocked. The proximal tip 31 of the needle 3 has a transverse slit 85, for the elastic penetration of the means of retention 84.

According to figure 1, and in a particular embodiment of the invention, the cleavable linking means 7 consists of an external, adhesive sleeve 71, which can be torn, for example, by shear action, using a tab 72. This sleeve 71 assembles two inner ends 51a and 52a of the two parts 51 and 52 of the flattened sheath 5, respectively adjacent to the separation zone 6.

For the so-called upper operating route, described hereinafter, the surgical assembly comprises, furthermore, a part 10 shown in figures 4 and 5, adapted to join two pieces 21 and 22 of the support tape 2 (cf. figures 18 through 21), obtained by transverse cutting of the latter.

This junction part 10, which is atraumatic, flat and flexible, comprises two opposing grasping means, for two adjacent ends 21a and 22a of two pieces 21 and 22, respectively. For this purpose, each grasping means 11 comprises, on the one hand, a locking means 12 of one end 21a or 22a (cf. figures 18 through 21) of the support tape 2, consisting of two flat jaws 12a and 12b, articulated along the same joining line, and on the other hand a means 13 of grabbing of the same end, consisting of a pin 13a on one 12b of the jaws, to pass through the tape 2, and a head 13b arranged on the other jaw 12a, which can snap onto the pin 13a.

Three different methods of emplacement or implementation of the surgical assembly as described above are now explained, namely and respectively, a method by so-called lower route, a method by so-called combined route, and a method by so-called upper route.

For each of these methods, one starts with the surgical assembly according to figures 1 to 3 in its connected or locked position, in which the needle 3 is connected by its proximal tip 31 to one of the joining pieces 9, that is, to one of the ends, for example 4a, of the composite strip 4, and this thanks to the previously described means of connection 8.

Turning now to the method of so-called lower route, and referring to figures 6 through 9:

- by introducing the needle 3 through the vagina 17, one makes the needle 3 penetrate in upward direction, at the patient's right side, avoiding the bladder 16; cf. figure 6.
- the composite strip 4 is thus engaged in the right course; cf. figure 7.
- one disconnects the needle 3 from the end 4a of the composite strip 4, to connect it to the end 4b of the same strip; then one makes the needle 3 penetrate in upward direction, at the patient's left side, again bypassing the bladder 16; cf. figure 8.
- one thus engages the composite strip 4 in the left course; when the latter forms a loop on the outside of the vagina 17, one cuts transversely the linking means 7 by clipping, to liberate the two parts 51 and 52 of the sheath 5; by pulling on the two joining pieces 9, one extracts the two parts 51 and 52 of the sheath 5, and one liberates the support tape 2, beneath the uterus 1.

Turning now to the combined route, and referring to figures 10 through 13:

- one makes the needle 3 penetrate in upward direction, at the patient's right side, avoiding the bladder 16, and emerging through the vagina 17; cf. figure 10.

- the composite strip 4 is then engaged in the right course, by penetration of the needle 3 in upward direction, on the patient's left side, bypassing the bladder 16; cf. figure 11.
- one thus engages the composite strip 4 in the left course; one disconnects the needle 3 from the composite strip 4; one cuts transversely the linking means 7 by clipping the outer sleeve 71, and one extracts from the latter outside of the vagina 17 (cf. figure 12);
- by traction on the two joining pieces 9, one extracts the two parts 51 and 52 of the sheath 5, and one liberates the support tape 2 in its course.

Turning now to the upper route, and referring to figures 14 through 21:

- - one makes the needle 3 penetrate in downward direction, at the patient's right side, from the abdominal wall 15, avoiding the bladder 16, and emerging through the vagina 17; cf. figure 14.
- the composite strip 4 is then engaged in the right course; when the linking means 7 is outside the vagina 17, one cuts the composite strip 4 on either side of the latter, so as to define two parts, one part 41 remaining in the right course, and one part 42 outside the vagina 17 (cf. figure 15);

- one then makes the needle 3 connected to the part 42 of the composite strip 4 penetrate in downward direction from the abdominal wall 15, on the left side, bypassing the bladder 16 (cf. figure 16);
- one thus engages the part 42 of the composite strip 4 in the left course, then one cuts the emerging portion of the part 42 of the composite strip 4, so as to separate the corresponding joining piece 9 from the rest of the strip 4 (cf. figure 17);
- by pulling on the ends 21a and 22a of the support tape 2, one exposes these latter with respect to the two parts 52 and 51, respectively, of the sheath 5; one can thus present the junction part 10 and proceed with the grasping of the two ends 21a and 22a (cf. figure 18);
- the junction part 10 thus joins, in safeguarded manner, the two ends 21a and 22a of the support tape 2, outside the vagina 17, as shown in figure 19;
- one then proceeds with a suprapubic traction on the right 41 and left 42 parts of the composite strip 4, so as to bring the junction part 10 into a suburethral position; one then pulls on the two parts 52 and 51 of the sheath 4, so as to liberate the support tape 2; cf. figure 20.
- the tape 2 is thus in retropubic and paravesicular position, whereas the atraumatic junction part 10 is in suburethral position (cf. figure 21).

As noted above, a surgical assembly according to the invention can be used regardless of the approach route or the operating technique chosen by the surgeon.

Thanks to the invention, the support tape 2 can be liberated at the last moment, after verifying the courses by cystoscopy.

If the course is found to be wrong, during the first pass and/or during the second pass, the operating procedure is reversible, either by disconnecting the needle 3 and retrograde traction on the sheath 5, or by complete traction on the composite strip 4.

As long as the sheath 5 has not been separated into its two parts 51 and 52, the surgical assembly according to the invention is reusable as many times as necessary, until the desired course has been obtained.

CLAIMS

1. Surgical assembly for supporting the urethra (1) in women, comprising a sub-urethral support tape (2) and a skin penetrating needle (3), characterized, in combination:
 - a) in that it contains a composite strip (4) which assembles at least the sub-urethral support tape (2) and a flattened protection sheath (5), said tape (2) being arranged, for example, freely inside this sheath (5);
 - b) the flattened sheath (5) has two parts (51, 52) along its length, arranged on either side of a zone of separation (6), in which is arranged a cleavable linking means (7) between said two parts;
 - c) the composite strip (4) contains at each of its two ends (4a, 4b) an identical part (81), for example, an identical female part, of a means of connection (8), which can be locked and unlocked, while the proximal tip (31) of the skin penetrating needle (3) contains another part (82), for example a male part, of said means of connection (8).
2. Assembly per claim 1, characterized in that the composite strip (4) has two joining pieces (9), each of them containing or incorporating said identical part (81) of the means of connection (8).
3. Assembly per claim 1, characterized in that the means of connection (8) has two elements, a male (82) and a female (81), which can snap together.
4. Assembly per claim 3, characterized in that the proximal tip (31) of the skin penetrating needle (3) is spatulate and each joining piece (9) of the flattened sheath (5) has a slit (83) adapted to

the penetration of said proximal spatulate tip (31), with a means of retention (84) of said tip, which can be manually locked or unlocked.

5. Assembly according to claim 4, characterized in that the proximal tip (31) of the skin penetrating needle (3) has a transverse slit (85) for the penetration of the means of retention (84).
6. Assembly per claim 1, characterized in that the cleavable linking means (7) comprises an outer adhesive sleeve (71), for example, one which can be torn by shear action, assembling the two inner ends (51a, 52a) of the two parts (51, 52) of the flattened sheath (5), respectively adjacent to the zone of separation (6).
7. Assembly per claim 1, characterized in that it further comprises a flat and flexible junction part (10) for two pieces (21, 22) of the support tape (2), obtained by transverse cutting of the latter, said part comprising two opposing means (11) for grasping of the two adjacent ends (21a, 22a) of the two pieces, respectively.
8. Assembly per claim 7, characterized in that each grasping means (11) comprises a means for locking (12) one end (21a, 22a) of the support tape (2).
9. Assembly per claim 7, characterized in that each grasping means (11) comprises a means (13) for grabbing one end (21a, 22a) of the support tape (2), for example, a pin (13a) that passes through the tape with a head (13b) which can snap onto said pin.
10. Assembly per claim 1, characterized in that the support tape (2) comprises a run-proof fillet stitch fabric, obtained with monofilaments or multifilaments of biocompatible synthetic material, for example, polypropylene or polyester.

11. Assembly per claim 1, characterized in that the support tape (2) is made in whole or in part from biological material or tissue, such as collagen.
12. Assembly per claim 1, characterized in that the protection sheath (5) is made from a synthetic material with low coefficient of friction, such as PTFE.

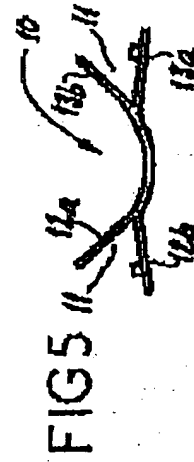
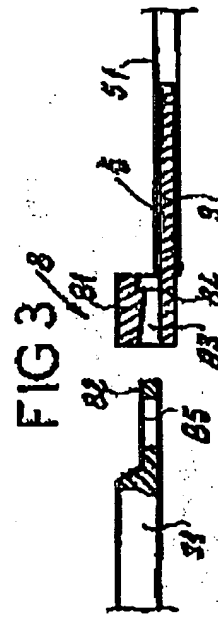
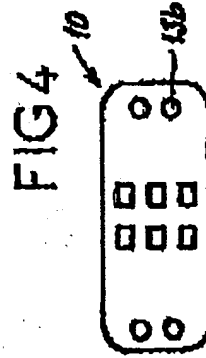
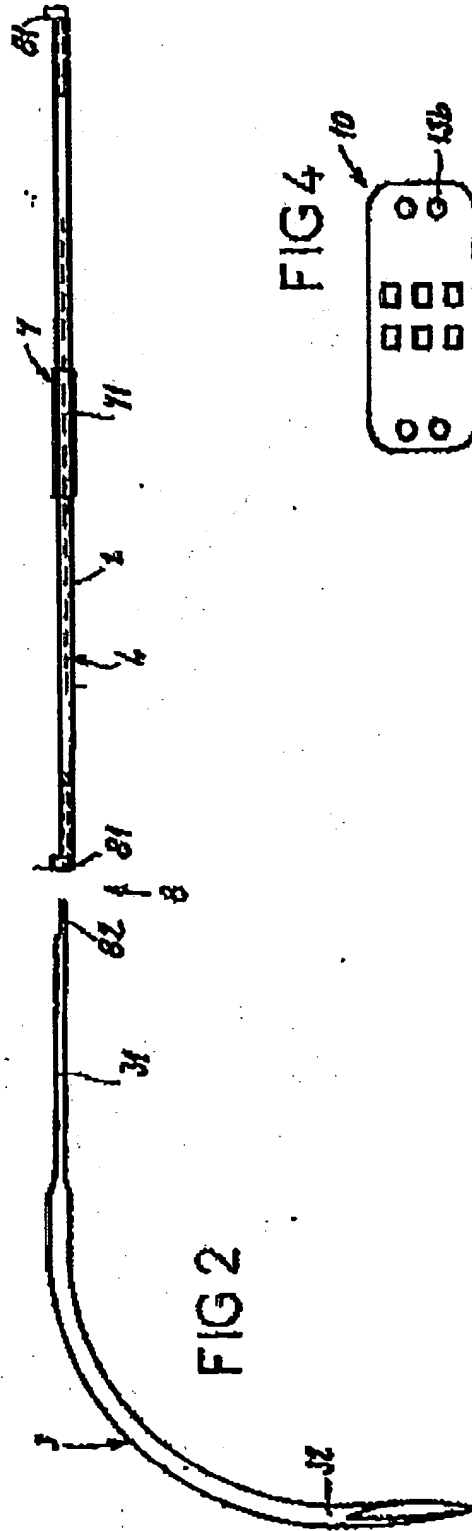
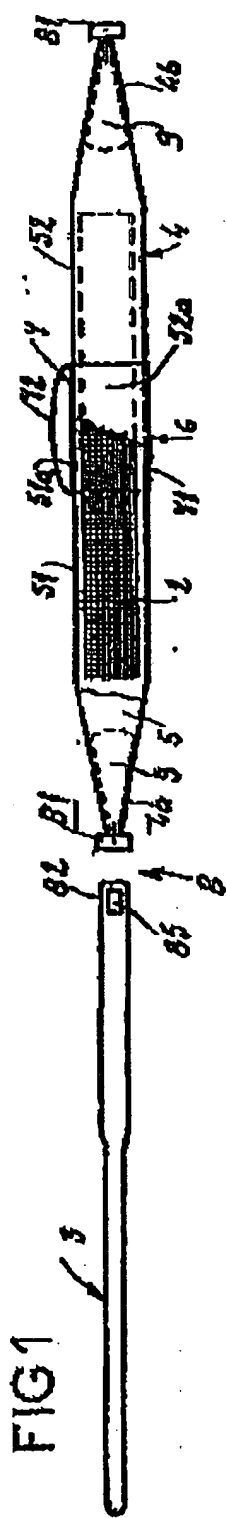


FIG 6

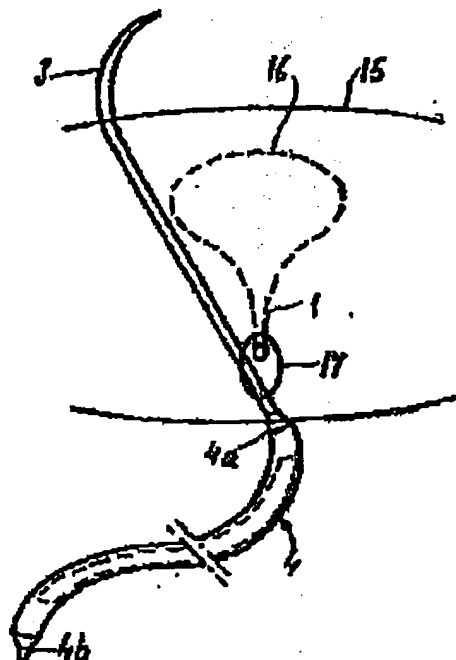


FIG 7

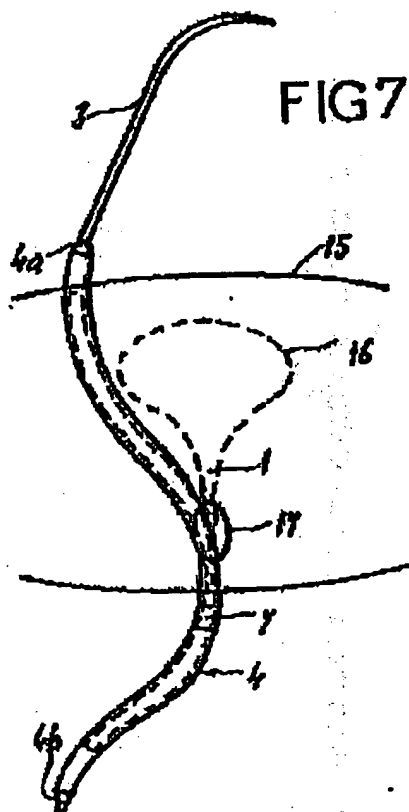


FIG 8

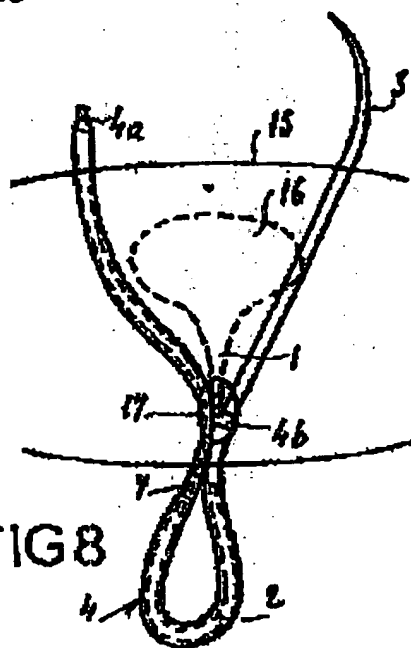
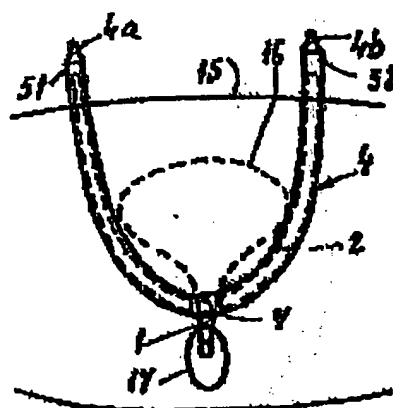


FIG 9



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FIG 10

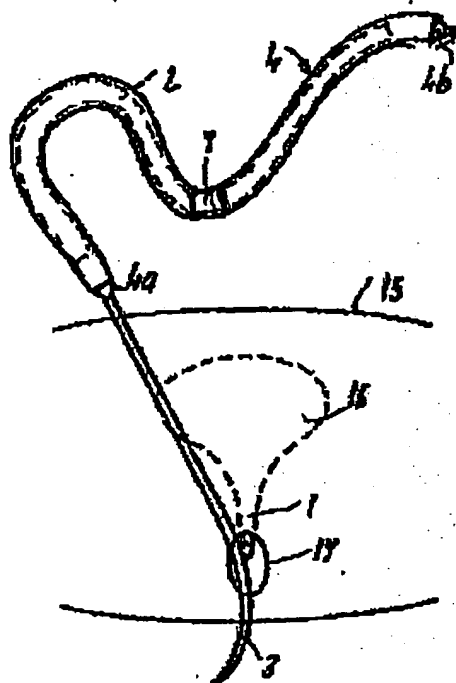


FIG 11

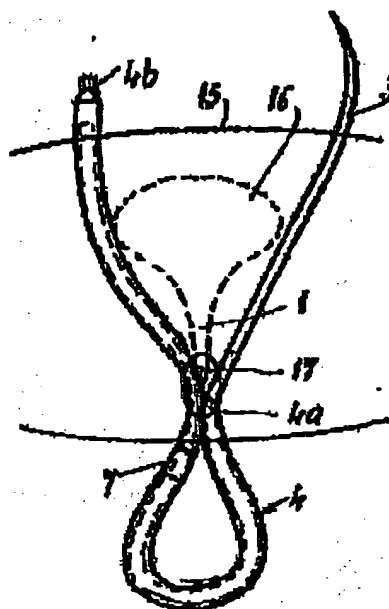


FIG 12

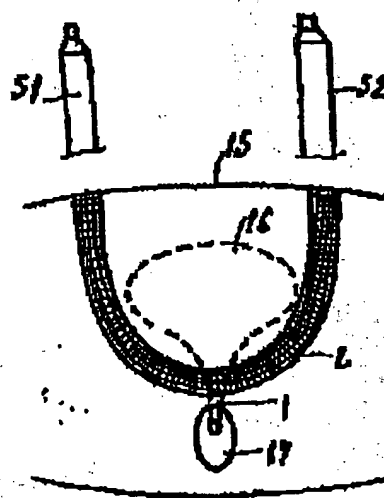
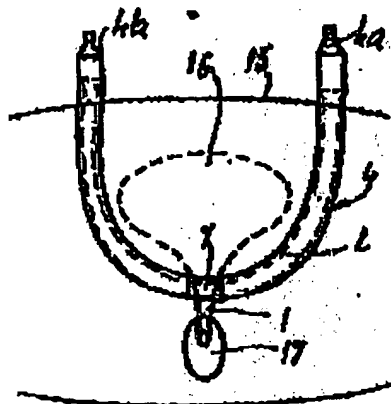


FIG 13

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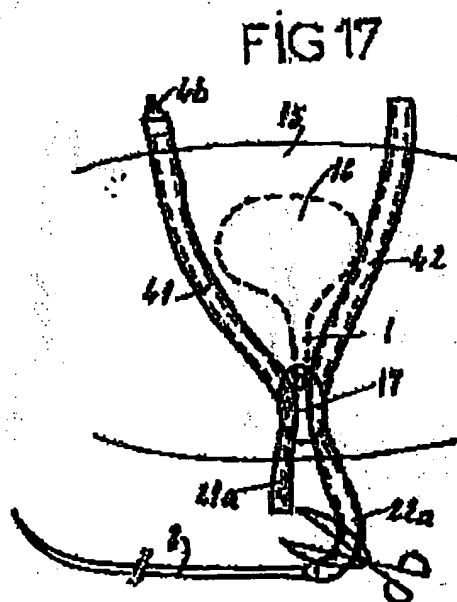
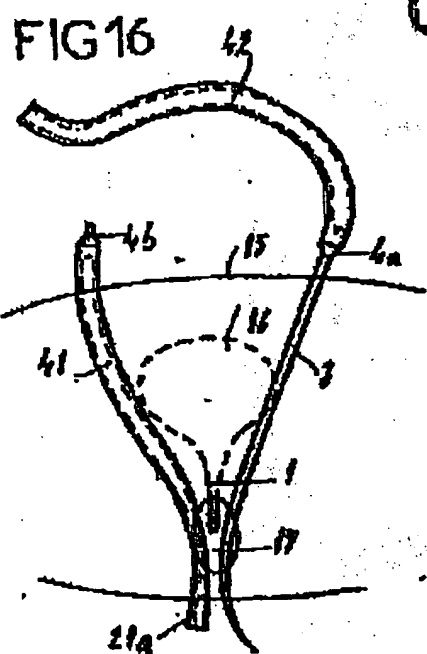
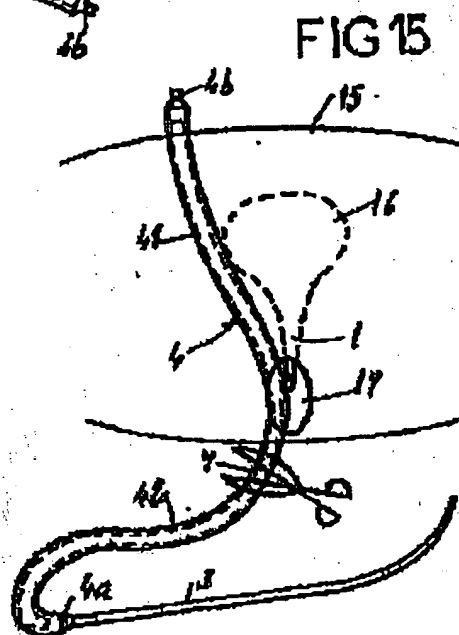
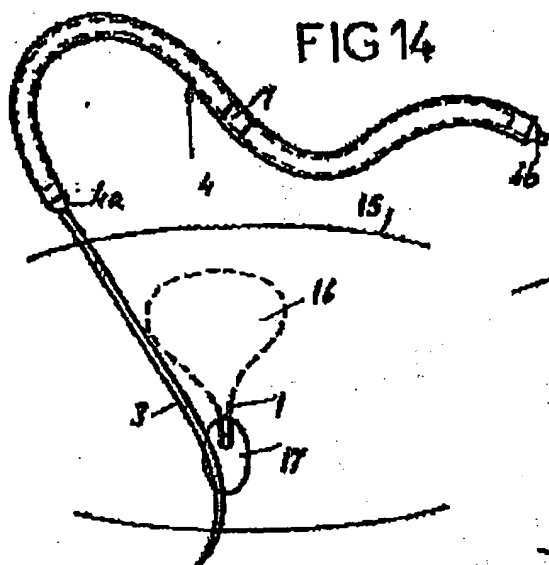


FIG 18

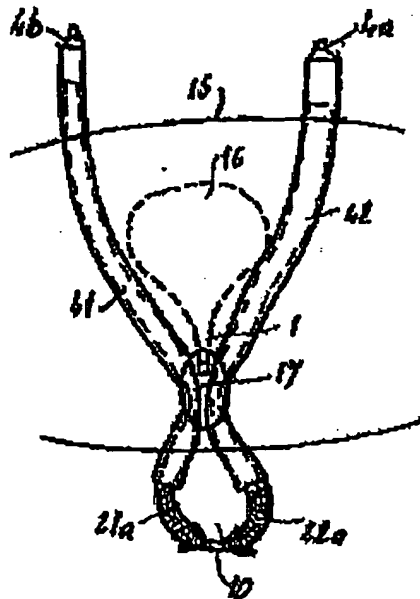


FIG 19

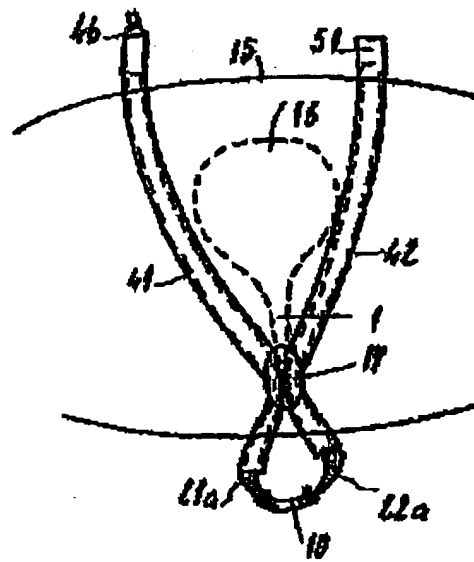


FIG 20

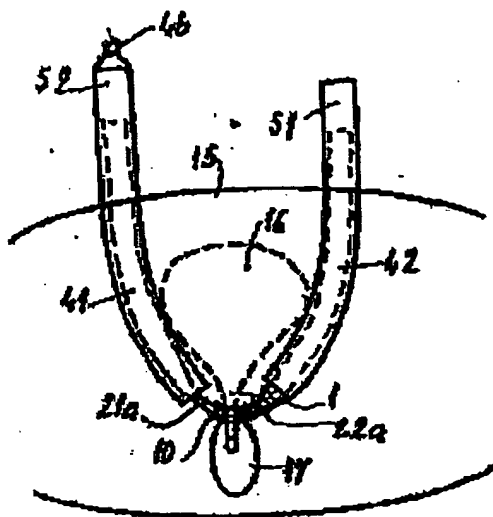
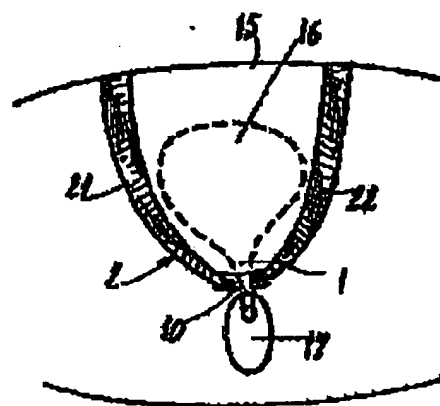


FIG 21



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